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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,394	11/18/2003	James R. Lisk JR.	2C03.1-071	4405

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EXAMINER

BUTLER, PATRICK

ART UNIT PAPER NUMBER

1732

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,394

Applicant(s)

LISK ET AL.

Examiner

Patrick Butler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 19-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20040517.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 15 July 2005 is acknowledged. The traversal is on the ground(s) that the criteria is not met that there must be a serious burden on the Examiner if restriction is required. This is not found persuasive because the inventions have acquired a separate status in the art as shown by the different classifications. Therefore, a serious burden would exist in the search for multiple separate inventions with their own separate status in the art instead of one invention.

The requirement is still deemed proper and is therefore made FINAL.

Additional restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 14-18, and 26-27 are drawn to "Plastic articles shaping and treating, classified in class 264, subclass 1.32.
- II. Claims 13, 19, 22-24 and 29, drawn to "IOLS", classified in class 623, subclass 6.56.
- III. Claims 25 and 28 are drawn to "Chemistry of Aromatic Structures, classified in class 260, subclass 350 R+.
- IV. Claim 20 is drawn to an apparatus, classified in class 425 and Claim 21 is drawn to a composition, classified in class 252.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as formulating a contact lens. See MPEP § 806.05(d).

Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as producing an item without utilizing the complexes of multivalent cations with aromatic structures. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Groups I, II is not required for Group III, restriction for examination purposes as indicated is proper.

Inventions [I and III] and [IV] are related as process and apparatus (the system) for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus or by hand, such as one that does not include removing phosphate buffer.

Additionally, inventions [IV] and [I and III] are related as product (the composition) and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product, such as one without a phosphate buffer.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, since the solution and system contains phosphate, which is not required to make the product, the two inventions have different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Groff on 02 August 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12, 14-18, and 26-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13, 19-25, 28, and 29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Additional restriction to one of the following inventions is required under 35 U.S.C. 121:

This application contains claims directed to the following patentably distinct species of the claimed invention: Group I - using solutions with multivalent cations and inducing formation of insoluble ionic materials (Claims 26 and 27) and Group II - solutions without multivalent cations and preventing formation of insoluble ionic materials (Claims 1-12 and 14-18).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Groff on 20 September 2005 a provisional election was made with traverse to prosecute the invention of Species Group II, claims 1-12 and 14-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26 and 27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The information disclosure statement filed 17 May 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the listed JP document has neither an abstract nor specification in the English language. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all

certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The term "elevated" in claim 10 and 18 is a relative term, which renders the claims indefinite. The term "elevated" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The temperature parameter has been rendered indefinite because of the relative terminology

For purposes of examination, the examiner interprets the term as applied to temperature as being greater than room temperature of about 21-23 degrees Celsius.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Šulc et al. (US Patent No. 4,893,913).

With respect to Claim 1, Šulc teaches treating a lens with a hydrophilic surface layer in a solution and washing the lens (processing an item at least partially formed of a hydrophilic polymeric material) so that the surface becomes protected from depositions of proteins (to produce a reduced protein affinity) (see col. 1, lines 52-63; col. 2, lines 8-16; and col. 3, lines 4-8). In the process taught by Šulc, embodiments of

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the first solution use salts such as sodium phosphate (see col. 2, lines 45-65). Because sodium phosphate is used as the alternative to calcium or magnesium chloride, formation of insoluble ionic materials is prevented principally because the components necessary to form insoluble ionic materials are not present (see Applicant's Specification, paragraph [00006]) (preventing the formation of insoluble ionic materials in or on the items during processing).

With respect to Claim 2, Šulc teaches swelling the outer surface (hydrating the item) (see col. 2, lines 13-16 and lines 56-65). The solution is free of multivalent cations as sodium phosphate may be used as the salt rather than the salts containing multivalent cations: calcium or magnesium chloride (see col. 2, lines 45-55). The treating occurs with sodium phosphate, which is a buffer (see col. 2, lines 56-65 and Applicant's Specification, paragraph [00022]) (processing the item in the presence of a buffer). The lens is rinsed with water (see col. 2, lines 8-13 and col. 3, lines 35 and 36) (flushing the buffer from the item using a solution free of multivalent cations).

With respect to Claim 8, Šulc teaches using sodium acetate (an acetate buffer) (see col. 2, lines 45-55).

With respect to Claim 9, Šulc teaches that a mixture of two or more salts can be employed, which would allow for sodium acetate and sodium phosphate to be employed (a buffer system of mixed anions) (see col. 2, lines 45-55).

With respect to Claim 10, the processing, that is treating and washing, is carried out above 50 degrees Celsius (see col. 3, lines 4-8) (the step of flushing the buffer from

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the item in a solution free of multivalent cations is carried out at a temperature greater than room temperature of about 21-23 degrees Celsius).

With respect to Claim 11, the processing includes additional swelling by immersion into physiologic saline (see col. 2, lines 23-27) (equilibrating the item in a saline solution).

With respect to claim 12, the treating solution teaches using sodium phosphate rather than calcium or magnesium chloride (the step of preventing the formation of insoluble ionic materials in or on the item during processing comprises the exclusion of multivalent cations from a processing solution).

Claim Rejections - 35 USC § 103

Claims 3-6 and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Šulc et al. (US Patent No. 4,893,913) as applied to claim 2 above, and further in view of Robinson (US Patent No. 6,095,901).

With respect to Claims 14, 3, and 5, Šulc teaches processing a lens (ocular item) as previously described.

Šulc does not explicitly teach utilizing glass-polishing beads to process a lens.

Robinson teaches polishing lens in slurry containing polishing beads, alumina, and a swelling agent (see col. 1, lines 40-44 and col. 4, lines 5-13). The polishing is done by tumble-polishing (see col. 5, lines 4-9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Robinson's polishing beads with Šulc's treating step in order to remove rough spots, sharp edges, and any tool or machining marks from the

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article's surfaces (see col. 4, lines 59-63). Moreover, Robinson specifically states that any agent capable of swelling the article to be polished without irreversibly damaging it will be suitable.

Šulc's treating step includes using sodium phosphate (see col. 2, lines 45-55) (a phosphorus buffer) as previously described.

With respect to Claims 4 and 15, Robinson teaches that the beads are preferable glass beads (see col. 3, lines 24-29) (glass polishing beads).

With respect to Claim 6 and 16, Šulc teaches that the treating solution is alkaline ([Claim 6] the item is processed in an alkaline aqueous solution; [Claim 16] maintaining the polishing slurry solution at a pH of at least 7) (see col. 2, lines 56 and 57).

With respect to Claim 17, Šulc teaches that the processing includes additional swelling by immersion into physiologic saline (equilibrating the item in a balanced saline solution) (see col. 2, lines 23-27).

With respect to Claim 18, Šulc teaches that the processing, that is treating and washing, is carried out above 50 degrees Celsius (see col. 3, lines 4-8) (the flushing step is carried out at a temperature greater than room temperature of about 21-23 degrees Celsius).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Šulc et al. (US Patent No. 4,893,913) in view of Robinson (US Patent No. 6,095,901) as applied to Claim 3 above, and further in view of Rankin (US Patent No. 3,767,788).

With respect to Claim 7, Šulc in view of Robinson teaches processing a lens as previously described. Šulc's treating step includes using sodium phosphate (see col. 2, lines 45-55) (a phosphorus buffer) as previously described.

Šulc and Robinson are silent as to the use of a borate buffer.

Rankin teaches that in ophthalmic solution useful for lens, it is useful to use sodium borate and sodium phosphate interchangeably to maintain basic pH (wherein the polishing slurry comprises a borate buffer) (see col. 1, lines 55-69 and col. 5, line 69 through col. 6, line 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Rankin's sodium borate in place of Šulc and Robinson's sodium phosphate because they are interchangeable to achieve the same end result of maintaining an alkaline pH. Moreover, due to the environmental degradation issues of algae bloom caused by phosphates, it would have been preferable to substitute any known substance in place of a phosphate if it would attain the same functionality in order to eliminate environmental liabilities from phosphate use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Butler whose telephone number is 571-272-8517. The examiner can normally be reached on Monday through Friday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 571-272-1196. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patrick Butler
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